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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,653	01/22/2004	Leonard Schlessinger	KAIS-0009	8542

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EXAMINER	
SIMS, JASON M	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 07/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/763,653	SCHLESSINGER ET AL.	
	Examiner	Art Unit	
	Jason M. Sims	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-60* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-60* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, 22, 31-40, and 52, drawn to a method, apparatus, and program storage device for estimating a virtual patient's plasma glucose level, classified in class 702, subclass 19.

II. Claims 11, 23, 41, and 53, drawn to a method, apparatus, and program storage device for estimating if a virtual patient has developed symptoms of type I diabetes, classified in class 702, subclass 19.

III. Claims 12-14, 24, 42-44, and 54, drawn to a method, apparatus, and program storage device for estimating if a virtual patient has developed symptoms of type II diabetes classified in class 702, subclass 19.

IV. Claims 15, 25, 45, and 55, drawn to a method, apparatus, and program storage device for estimating a virtual patient's hemoglobin A_{1c} classified in class 702, subclass 19.

V. Claims 16, 26, 46, and 56, drawn to a method, apparatus, and program storage device for estimating a virtual patient's randomly measured blood glucose level classified in class 702, subclass 19.

VI. Claims 17-18, 27, 47-48, and 57, drawn to a method, apparatus, and program storage device for estimating a virtual patient's tolerance to an oral glucose level load at age t classified in class 702, subclass 19.

VII. Claims 19, 28, 49, and 58, drawn to a method, apparatus, and program storage device for estimating a virtual patient's thirst level at time x classified in class 702, subclass 19.

VIII. Claims 20, 29, 50, and 59, drawn to a method, apparatus, and program storage device for estimating the probability of occurrence of diabetic ketoacidosis events for a virtual patient classified in class 702, subclass 19.

IX. Claims 21, 30, 51, and 60, drawn to a method, apparatus, and program storage device for estimating the probability of a moderate or severe hypoglycemic event in a virtual patient classified in class 702, subclass 19.

Inventions I-IX` are directed to related subject matter of a virtual patient, the patient's relationship with glucose, ketoacidosis, thirst, and hemoglobin. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, groups I-IX all involve methods, which have unique steps and mathematical equations and therefor have different modes of operation, are of different design, function, and effect. For example, Group I is directed to a method, apparatus, and program storage device for estimating a virtual patient's plasma glucose level, which is a different goal from the other groups. Group II is directed to a method,

apparatus, and program storage device for estimating if a virtual patient has developed symptoms of type I diabetes, which is a different goal from the other groups. Group III is directed to a method, apparatus, and program storage device for estimating if a virtual patient has developed symptoms of type II diabetes, which is a different goal from the other groups. Group IV is directed to a method, apparatus, and program storage device for estimating a virtual patient's hemoglobin A_{1c}, which is a different goal from the other groups. Group V is directed to a method, apparatus, and program storage device for estimating a virtual patient's randomly measured blood glucose level, which is a different goal from the other groups. Group VI is directed to a method, apparatus, and program storage device for estimating a virtual patient's tolerance to an oral glucose level load at age t, which is a different goal from the other groups. Group VII is directed to a method, apparatus, and program storage device for estimating a virtual patient's thirst level at time x, which is a different goal from the other groups. Group VIII is directed to a method, apparatus, and program storage device for estimating the probability of occurrence of diabetic ketoacidosis events for a virtual patient, which is a different goal from the other groups. Group IX is directed to a method, apparatus, and program storage device for estimating the probability of a moderate or severe hypoglycemic event in a virtual patient, which is a different goal from the other groups.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Andrew Wang can be reached via telephone (571)-272-0811.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Any inquire of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tiffany Tabb, whose telephone number is (571)-272-0556.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AU 1631 examiner
6/26/06